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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,852	05/31/2001	Claus Froberg	514413-3864	5091

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/02/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,852

Applicant(s)

FROHBERG, CLAU S

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-21 and 24-25 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the process of Claim 21 contained in Group I and the starch of Group ^PII have unity of invention. This is not found persuasive because the nucleotide sequence and starch do not share a special technical feature. The election of species with respect to Claim 2 b) is deemed proper because the nucleotide sequences have acquired a separate status in the art as shown by their different classifications, recognized divergent subject matter, and because the search required for one of the groups is not required for another restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 6 is objected to because of the following informalities: It appears that "[lacuna]" does not belong in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a nucleic acid molecule of SEQ ID NO: 1 encoding a protein encompassing SEQ ID NO: 2 or its derivatives or parts; nucleic acid molecules encompassing SEQ ID NO: 1 and its derivatives or parts and that hybridize or are complementary therewith; degenerate versions thereof; and vectors comprising said nucleic acid sequences.

Applicant describes SEQ ID NO: 1 encoding SEQ ID NO: 2.

Applicant does not describe any other DNA sequence other than SEQ ID NO: 1 encoding the amino acid of sequence SEQ ID NO: 2.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

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Given the failure of the DNA and DNA derivatives and parts encoding any beta amylase or derivatives or parts to be adequately described, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-111.

Claims 1-21 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cDNA fragment comprising SEQ ID NO: 1 or encoding potato beta amylase of SEQ ID NO: 1; transformation and regeneration of a potato plant comprising said cDNA fragment; and modified starch in transgenic potato transformed with said cDNA fragment does not reasonably provide enablement for any other DNA sequences other than SEQ ID NO: 1 or those that encode SEQ ID NO: 2, or for modifying starch in any other plant other than potato. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a process for making plants that synthesize a modified starch when transformed with a nucleic acid molecule of SEQ ID NO: 1 encoding a protein encompassing SEQ ID NO: 2 or its derivatives or parts; nucleic acid molecules encompassing SEQ ID NO: 1 and its derivatives or parts and that hybridize or are complementary therewith; degenerate versions thereof either natural or synthetic; or vectors comprising said nucleic acid sequences.

Applicant teaches isolation from a lambda zap cDNA potato library of a cDNA fragment encoding potato beta amylase of SEQ ID NO: 1 (Example 1 page 42); transformation and

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regeneration of a potato plant comprising SEQ ID NO: 1 from Example 1 (Example 12 page 45); modified starch in transgenic potato (Example 13 page 45).

Applicant does not teach any other DNA sequences other than SEQ ID NO: 1 or that encode SEQ ID NO: 2, or for modifying starch in any other plant other than potato.

Isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, *Plant Molecular Biology* 40:857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65⁰C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

The unpredictability in attempting to engineer modified branching in starch using a transgenic approach is illustrated in the example where constructs carrying an isoform of a starch branching enzyme cDNA in antisense orientation was introduced into potato, neither the amylose content of the starch in the tubers, nor the total starch content of the tubers was altered (Willmitzer *et al.*, *Plant Polymeric Carbohydrates*, 17/1993, pp. 33-39, page 38 lines 17-21). Another attempt to modify starch using an antisense construct comprising the GBSS II gene from potato resulted in no effect whatsoever on the starch even when the level of GBSS II protein was

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very low (Kossmann J. *et al.*, Progress in Biotechnology, 10, Proc. Int. Conf. 4/23-26/95 1995, pp. 271-278 on page 275, lines 11-27)

Generally speaking, the possible and most likely presence of uncharacterized multiple isoforms of starch metabolic enzymes expressed in various tissue types of a plant through the developmental phases of growth, especially during storage of starch, and given the polyploidic nature of many crop plants; transformation with a single isoform of a starch metabolic gene is a highly unpredictable factor to consider in any attempt to reduce gene expression using an antisense or sense strategy.

Given the lack of guidance for isolating derivatives and parts of nucleic acids encoding amino acids with the function of a beta amylase, the absence of working examples in the specification, the breadth of the claims, and the unpredictability in the art, undue trial and error experimentation would have been required by one skilled in the art to transform and regenerate a plant with sense or antisense beta-amylase constructs and evaluate a multitude of non-exemplified regenerated plants for modified starch. Undue experimentation would have also been required to isolate a multitude of non-exemplified derivatives or parts from a multitude of sources, or to design a multitude of non-exemplified sequence fragments or variants, and to evaluate their ability to modify starch in transformed plants.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-21 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in the rejection.

At Claim 1, line 8, “preferably which hybridize specifically” is indefinite.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation hybridize with, and the claim also recites preferably which hybridize specifically which is the narrower statement of the range/limitation.

At Claim 6, lines 1-2, “preferably specifically hybridizes” is indefinite.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

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USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation hybridizes, and the claim also recites preferably specifically hybridizes which is the narrower statement of the range/limitation.

At Claim 10, lines 3-4, "partly present in sense orientation and partly in antisense orientation". It is unclear whether the same part (i.e. complementary parts) or different parts of SEQ ID NO: 1 are in antisense and sense orientation within the vector.

At Claim 21, line 1, "A process for the production of starch by a method known *per se*" is indefinite. The language used fails to describe any method steps whereby the said known method is in any way modified or altered as a result of the introduction of DNA into the process for the production of starch.

At Claim 24, line 3, "preferably bacterial or plant cells" is indefinite.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by

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"such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 24 recites the broad recitation transgenic celss, and the claim also recites preferably bacterial or plant cells which is the narrower statement of the range/limitation.

Claims 24-25 provide for the use of nucleic acid molecules or plant cells, respectively, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 24-25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 8 recites the limitation "wherein the nucleotide sequence encoding a protein with the function of a soluble starch synthase III or parts thereof" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The DNA of Claim 1, since it has not been isolated by the hand of man reads as a product of nature, thus falling outside the five classes of patentable subject matter.

The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida N. *et al.*, Journal of Biochemistry, 1991, Vol. 110, pp. 196-201.

The claims are indefinite and broadly drawn as discussed supra. The derivatives or parts of the claimed sequences read upon other DNA sequences that encode functional beta amylases from any source either natural or synthetic.

Yoshida teaches the cloning, sequencing, and expression in *E. coli* of sweet potato beta-amylase (Abstract). Thus the reference teaches all the limitations of Claims 1-12 and 24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor M. *et al.*, WO 97/24448 published July 10, 1997 in view of Yoshida N. *et al.*, Journal of Biochemistry, 1991, Vol. 110, pp. 196-201.

The claims are indefinite and broadly drawn as discussed supra. The derivatives or parts of the claimed sequences read upon other DNA sequences that encode functional beta amylases from any source either natural or synthetic in either sense or antisense orientation for modifying starch in a plant.

Applicant broadly claims a process for making plants that synthesize a modified starch when transformed with a nucleic acid molecule of SEQ ID NO: 1 encoding a protein encompassing SEQ ID NO: 2 or its derivatives or parts; nucleic acid molecules encompassing SEQ ID NO: 1 and its derivatives or parts and that hybridize or are complementary therewith;

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degenerate versions thereof either natural or synthetic; or vectors comprising said nucleic acid sequences.

Taylor teaches potato with modified starch transformed with antisense glucosidase cDNA (Example 6 pages 18-19).

Taylor does not teach a beta-amylase cDNA.

The teachings of Yoshida are discussed supra.

It would have been obvious at the time of Applicant's invention to modify the invention of Taylor to include a plasmid comprising a beta-amylase cDNA or derivative or part thereof as taught by Yoshida for modifying potato starch. One of skill in the art would have been motivated by the knowledge common in the art that the beta-amylase cDNA and derivatives and parts thereof are valuable materials for genetic engineering of plants and the success of Taylor in modifying starch in potato, and that one would have had a reasonable expectation of success of expressing genes in transformed plants and plant cells. The choice of a gene encoding one of the carbohydrate metabolizing enzymes would have been an obvious design choice.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

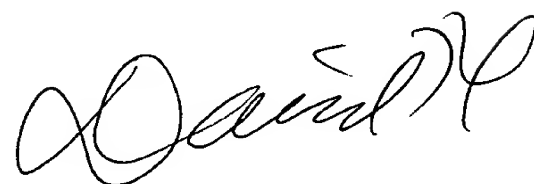
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Russell Kallis Ph.D.
December 22, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written in black ink.